IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of	) Examiner: Scott David Priebe
Robert J. Levy et al.	) Art Unit: 1633
Serial No. 10/656,068	) Our File No: CHOP.0100.1
Filed: September 5, 2003	)
For: "Methods and Compositions for Enhancing the Delivery of a Nucleic Acid to a Cell"	)

TRAVERSAL AND REQUEST FOR

RECONSIDERATION OF REQUIREMENT FOR RESTRICTION

At the outset it is noted that a shortened statutory response period of one (1) month was set forth in the Official Action dated October 28, 2005 in the above-identified patent application. Therefore, the initial due date for response was November 28, 2005. A petition for a three (3) month extension of the response period is presented with this response, which is being filed within the three month extension period.

A restriction requirement under 35 U.S.C. §121 was set forth in the October 28, 2005 Official Action. It is the Examiner's position that claims 34-66 in the present application are drawn to twenty-seven (27) patentably distinct inventions which are as follows:

Group I: Claims 35, 40, 46, 51, 60, and 65, drawn to methods for enhancing delivery of a nucleic acid encoding a polypeptide to a cell using denatured collagen;

Group II: Claims 35, 46, and 60, drawn to methods for enhancing delivery of a nucleic acid encoding a polypeptide to a cell using cytochalasin;

Group III: Claims 37, 38, 48, 49, 62, and 63, drawn to methods for enhancing delivery of a nucleic acid encoding a polypeptide to a cell using integrin $\alpha_v\beta_3$;

Group IV: Claims 37, 48, and 62, drawn to methods for enhancing delivery of a nucleic acid encoding a polypeptide to a cell using integrin $\alpha_2\beta_1$;

Group V: Claims 37, 48, and 62, drawn to methods for enhancing delivery of a nucleic acid encoding a polypeptide to a cell using integrin $\alpha_8\beta_1$;

Group VI: Claims 37, 48, and 62, drawn to methods for enhancing delivery of a nucleic acid encoding a polypeptide to a cell using integrin $\alpha_9\beta_1$;

Group VII: Claims 37, 48, and 62, drawn to methods for enhancing delivery of a nucleic acid encoding a polypeptide to a cell using integrin $\alpha_9\beta_3$;

Group VIII: Claims 37, 48, and 62, drawn to methods for enhancing delivery of a nucleic acid encoding a polypeptide to a cell using integrin $\alpha_v\beta_6$;

Group IX: Claims 35, 46, and 60, drawn to methods for enhancing delivery of a nucleic acid encoding a polypeptide to a cell using an ion channel blocker;

Group X: Claims 35, 46, and 60, drawn to methods for enhancing delivery of a nucleic acid encoding a polypeptide to a cell using a beryllium fluoride or cadmium salt;

Group XI: Claims 36, 47, and 61, drawn to methods for enhancing delivery of a nucleic acid encoding a polypeptide to a cell using a modulator of Erk1/Srf complex;

Group XII: Claims 36, 47, and 61, drawn to methods for enhancing delivery of a nucleic acid encoding a polypeptide to a cell using a modulator of JNK activated AP-1;

Group XIII: Claims 39, 50, and 64, drawn to methods for enhancing delivery of a nucleic acid encoding a polypeptide to a cell using a modulator of Fak;

Group XIV: Claims 39, 50, and 64, drawn to methods for enhancing delivery of a nucleic acid encoding a polypeptide to a cell using a modulator of Src;

Group XV: Claims 39, 50, and 64, drawn to methods for enhancing delivery of a nucleic acid encoding a polypeptide to a cell using a modulator of Grb2;

Group XVI: Claims 39, 50, and 64, drawn to methods for enhancing delivery of a nucleic acid encoding a polypeptide to a cell using a modulator of Ras;

Group XVII: Claims 39, 50, and 64, drawn to methods for enhancing delivery of a nucleic acid encoding a polypeptide to a cell using a modulator of Sos;

Group XVIII: Claims 39, 50, and 64, drawn to methods for enhancing delivery of a nucleic acid encoding a polypeptide to a cell using a modulator of Raf;

Group XIX: Claims 39, 50, and 64, drawn to methods for enhancing delivery of a nucleic acid encoding a polypeptide to a cell using a modulator of Cav;

Group XX: Claims 39, 50, and 64, drawn to methods for enhancing delivery of a nucleic acid encoding a polypeptide to a cell using a modulator of Shc;

Group XXI: Claims 39, 50, and 64, drawn to methods for enhancing delivery of a nucleic acid encoding a polypeptide to a cell using a modulator of Cdc42;

Group XXII: Claims 39, 50, and 64, drawn to methods for enhancing delivery of a nucleic acid encoding a polypeptide to a cell using a modulator of Rac;

Group XXIII: Claims 39, 50, and 64, drawn to methods for enhancing delivery of a nucleic acid encoding a polypeptide to a cell using a modulator of RhcA;

Group XXIV: Claims 39, 50, and 64, drawn to methods for enhancing delivery of a nucleic acid encoding a polypeptide to a cell using a modulator of MEK;

Group XXV: Claims 39, 50, and 64, drawn to methods for enhancing delivery of a nucleic acid encoding a polypeptide to a cell using a modulator of MAPK;

Group XXVI: Claims 39, 50, and 64, drawn to methods for enhancing delivery of a nucleic acid encoding a polypeptide to a cell using a modulator of MRK1; and

Group XXVII: Claims 39, 50, and 64, drawn to methods for enhancing delivery of a nucleic acid encoding a polypeptide to a cell using a modulator of MRK2.

The Examiner indicates that claims 34, 41-45, 52-59, and 66 link Groups I-XXVII, claims 35, 46, and 60 link Groups III-VIII, and claims 35, 46, and 60 link Groups XIII-XXVII.

Applicants submit that a withdrawal of the restriction requirement, or at least a modification of the restriction requirement, is clearly in order.

According to the MPEP at §803, two criteria must be satisfied in order to warrant restriction:

1) the inventions must be **independent and distinct** as claimed; **and**
2) there must be a **serious burden** on the Examiner if the restriction is not required. [Emphasis added.]

Further, the MPEP §802.01 defines the terms "independent" and "distinct" as:

INDEPENDENT

> The term "independent" (i.e., not dependent) means that there is no disclosed relationship between the two or more subjects disclosed, that is, they are unconnected in design, operation, or effect, for example: (1) species under a genus which species are not usable together as disclosed; or (2) process and apparatus incapable of being used in practicing the process.

DISTINCT

> The term "distinct" means that two or more subjects as disclosed are related, for example, as combination and part (subcombination) thereof, process and apparatus for its practice, process and product made, etc., but are capable of separate manufacture, use, or sale as claimed, AND ARE PATENTABLE (novel and unobvious) OVER EACH OTHER (though they may each be unpatentable because of the prior art). It will be noted that in this definition the term related is used as an alternative for dependent in referring to subjects other than independent subjects.

Notwithstanding the Examiner's assertion to the contrary, it is apparent from an objective reading of Groups I to XXVII that they are drawn to closely related subject matter and, therefore, do not comprise separate and distinct inventions. In order to be considered independent, there must be no "disclosed relationship" between the two or more subjects,

i.e., they are unconnected in "design, operation, or effect." Applicants submit that the claims of Groups I to XXVII are clearly drawn to methods of increasing the delivery of a nucleic acid molecule to a cell. Furthermore, the agents recited in Groups I to XXVII achieve the goal of enhancing nucleic acid delivery to cells by the same mechanism, namely increasing cytoskeletal permissiveness by enhancing the effective level of G-actin (see, e.g., page 20, line 26 through page 24, line 25). Accordingly, Applicants submit that it is clear that Groups I to XXVII have a "disclosed relationship" and are connected in design, operation, and effect.

Additionally, "if the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions" (MPEP at §803). Notwithstanding the Examiner's assertion to the contrary, it is apparent from an objective reading of Groups I to XXVII that they are drawn to closely related subject matter and the examination of Groups I to XXVII together cannot be reasonably regarded as imposing a "serious burden" on the Examiner. Indeed, each of Groups I to XXVII has been classified in the same class and subclass.

Applicants also note that claims 34, 45, and 59 have not been accounted for in the instant restriction requirement. Inasmuch as these claims are the broad independent claims from which all of the other claims depend, it appears that these claims should be included in each of Groups I to XXVII.

For the foregoing reasons, Applicants respectfully request withdrawal or, at the very least, modification of the present restriction requirement.

In order to be fully responsive to the instant restriction requirement, Applicants hereby elect, with traverse, Group I, namely claims 35, 40, 46, 51, 60, and 65, and presumably claims 34, 45, and 59, drawn to methods for

enhancing delivery of a nucleic acid encoding a polypeptide to a cell using denatured collagen.

Applicants hereby reserve the right to file one or more continuing applications, as provided in 35 U.S.C. §120, on the subject matter of any claims finally held withdrawn from consideration in this application.

Early and favorable action on the merits of this application is respectfully solicited.

Respectfully submitted,
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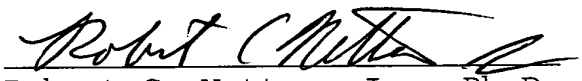
By 
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